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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/788,280	02/15/2001	Davis S. Burt	405352000600	5295

25225 7590 10/08/2002
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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/08/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/788,280

Applicant(s)

BURT ET AL.

Examiner

Ulrike Winkler, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-57 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 15.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Election/Restrictions

After mailing the previous Election/Restriction requirement (Paper No. 13) applicant's representative telephoned the office indicating that a preliminary amendment comprising claims 35-57 has not been considered as the claims were not included in the Election/Restriction requirement. Upon review of the file it was discovered that the preliminary amendment was not present in the file. Applicant faxed a courtesy copy of the preliminary amendment filed on June 7, 2002. In view of the newly added claims the following new Election/Restriction requirement is made. The office apologizes for any inconvenience this may have caused applicant.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 14-22, 35-49, 56 drawn to a method of preparing a vaccine by combining an antigen in with a proteosome in the presence of a detergent followed by removing the detergent, classified in class 424, subclass 206.1.
- II. Claims 23-27, 57 drawn to a method of eliciting an immune response against an infectious agent such as influenza, classified in class 424, subclass 9.2.
- III. Claims 28-30, drawn to an improved method of preparing proteosomes, classified in class 530, subclass 412.
- IV. Claims 9-13, 31-34, drawn to a composition a vaccine against an infectious agent, such as influenza, classified in class 424, subclass 209.1.
- V. Claims 50, 51, 54, 55, drawn to a composition a vaccine against an allergen, classified in class 424, subclass 275.1.

- VI. Claims 50, 52, drawn to a composition a vaccine against a cancer antigen, classified in class 424, subclass 277.1.
- VII. Claims 50, 53 drawn to a composition a vaccine against a biologic threat agent, classified in class 424, subclass 236.1.
- VIII. Claim 57, drawn to a method of preventing or treating allergies, classified in class 424, subclass 9.2.
- IX. Claim 57, drawn to a method of preventing or treating cancer, classified in class 424, subclass 9.2.
- X. Claim 57, drawn to a method of preventing or treating exposure to a biologic threat agent, classified in class 424, subclass 9.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups IV-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise different epitopes, which are from structurally different pathogens that have different pathologies and disease processes. For example, the vaccination with an influenza antigen will not provide protection against cancer.

Groups I-III and VIII-X are drawn to methods and each is distinct from the other because they utilize different starting materials, therefore the outcomes are not be expected to be the same. Groups I is drawn to a method of preparing a vaccine utilizing an antigen and a proteosome in the formulation of the vaccine. Group II is drawn to a method of eliciting an

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immune response in a subject, the end product is protection of the subject from the virus. Group III is drawn to a method of preparing a proteosome, the end product is a purified proteosome. Group VIII is drawn to the method of treating allergies. Group IX is drawn to a method of treating cancer. Group X is drawn to a method of treating exposure to a biologic threat agent. Though there may be overlap between these methods in question for groups I-III and VIII-X each utilizes different materials and therefore the outcome is expected to be different.

Inventions I and II are related as product of making the product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of vaccination using the product formulation of a proteosome can be achieved with a recombinant virus, or another adjuvant formulation.

Inventions I and VIII are related as product of making the product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of vaccination using the product formulation of a proteosome can be achieved with another adjuvant formulation containing an allergen.

Inventions I and IX are related as product of making the product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

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process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of vaccination using the product formulation of a proteosome can be achieved with another adjuvant formulation containing a cancer antigen.

Inventions I and X are related as product of making the product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of vaccination using the product formulation of a proteosome can be achieved with another adjuvant formulation containing a toxin.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter which requires different searches of the non-patent literature, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Ulrike Winkler, Ph.D. 10/7/02